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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,945	10/20/2000	Nobuyuki Itoh	PL08243.001/201130.407	6477

27476 7590 09/24/2003

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EXAMINER
ROMEO, DAVID S

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/24/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/692,945	ITOH ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 28-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2½,4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *RAW SEQUENCE LISTING* .

DETAILED ACTION

Claims 1-52 are pending.

Applicant's election with traverse of group V, claims 24-27, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search the use of both the human and rat FGF-20. This is not found persuasive because there are no claims directed to the method of group V that use rat FGF-20. Furthermore, human and rat FGF-20 are different proteins and structurally distinct chemical compounds. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such polypeptide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-23, 28-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Specification

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence

identifiers at each place where a sequence is discussed. See figure 1 and page 17, full paragraph 1. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Applicant may bring the figure(s) into compliance by amending either the figure(s) or the "Brief Description of the Drawings" to recite the appropriate sequence identifier.

Correction is required.

The computer readable form of the sequence listing filed March 27, 2003 has been entered after correction of minor errors in the CRF by the Scientific and Technical Information Center staff. Specifically, Non-ASCII "garbage" at the end of the file was deleted. See the raw sequence listing (attached).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 24 is rejected under 35 U.S.C. 102(e) as being anticipated by Jeffers (A). This rejection is based upon an effective filing date of July 27, 1999 for Jeffers.

Jeffers discloses a FGF-CX polypeptide comprising an amino acid sequence that is identical to the amino acid sequence of the present application's SEQ ID NO: 4. See Figure 4, FGF-CX, SEQ ID NO: 2. Jeffers also discloses that FGF-CX may be used in treating glial cell related disorders. The glial-cell modulating activity of FGF-CX may be as a neuroprotective-like activity, and FGF-CX may be used as a neuroprotective agent. See page 30, paragraph 294. Use of FGF-CX as a neuroprotective agent has been construed by the examiner to encompass "providing trophic support" for glial cells, in the absence of evidence to the contrary. A patient with a glial cell related disorder has been construed by the examiner to encompass a patient in need of neuroprotective-like activity, in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 112

Claims 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing the survival of

dopaminergic neurons, does not reasonably provide enablement for providing trophic support for cells with out regard to the cell type or for restoring the function of or increasing the number of dopaminergic neurons. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to or encompass a method of providing trophic support for any and/or all cells by administering FGF-20 (SEQ ID NO: 4) or a method of restoring the function of or increasing the number of dopaminergic neurons by administering FGF-20.

FGFs are local signal molecules that act on proximal cells (the present specification at paragraph bridging pages 10-11). FGF-20 is expressed in the brain but not in other tissues (the present specification at page 21, full paragraph 1). These teachings suggest that FGF-20 is brain-specific, whereas the claims are directed to or encompass a method of providing trophic support for any and/or cells. In general the activity of FGFs is unpredictable. See Xie (U), wherein it is taught that in contrast to FGF-1 and several other FGFs tested, FGF-19 demonstrated little mitogenic activity (page 731, left column, full paragraph 1). FGFs regulate cell survival, apoptosis, proliferation, differentiation, matrix composition, chemotaxis, cell adhesion, migration, and growth of cell processes. Different cell types, or even the same cell, may display alternate, sometimes opposite responses to FGFs, depending on the state of differentiation, biochemical status, and the cellular, physical, and chemical environment of the cell. Besides the multiple effects of each FGF isotype, different FGFs and their splice variants may have distinct actions. See Szebenyi (V), page 72, full paragraph 1.

The no working examples in the present specification of providing trophic support to a cells other than dopaminergic neurons.

Restoring the function of dopaminergic neurons encompasses restoring the function of irreversibly damaged, dead, or dying dopaminergic neurons. The present specification does not provide any information regarding restoring the function of irreversibly damaged, dead, or dying dopaminergic neurons. Nor does the present specification provide any information regarding increasing the number of dopaminergic neurons. Enhancing the survival of dopaminergic neurons is not commensurate in scope with either restoring the function of irreversibly damaged, dead, or dying dopaminergic neurons or increasing the number of dopaminergic neurons.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements, while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

To practice the instant invention in a manner consistent with the breadth of the claims would not require just s repetition of work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which

would involve the determination of cell types, the state of differentiation, biochemical status, and the cellular, physical, and chemical environment of the cells required to achieve the claimed method results. It is this additional characterization of FGF-20 that is required in order to meet the limitations of the present claims that constitutes undue experimentation.

In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Conclusion

No claims are allowable.

The following amendments are suggested:

Cancel claims 1-23, 28-52.

Replace claim 24 with the following claim:

24. A method of enhancing the survival of dopaminergic neurons in a patient in need thereof, the method comprising administering to the patient a composition comprising a polypeptide comprising the amino acid sequence of SEQ ID NO: 4.

Replace claim 27 with the following claim:

27. A method of alleviating a disease condition in the brain of a human patient wherein said disease condition is alleviated by enhancing the survival of

dopaminergic neurons in said human patient, said method comprising administering to said patient a pharmaceutically effective composition comprising a polypeptide having the amino acid sequence of SEQ ID NO: 4.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
SEPTEMBER 21, 2003